REMARKS

Applicants amend independent claims 1, 33 and 50. As discussed in more detail below, support for the amendments can be found in the specification. The application is now believed to be in condition for allowance. Reconsideration and allowance are respectfully requested.

Rejections Under 35 U.S.C. 103

The Office Action rejects claims 1, 4-8, 10-19, 21-28, 31, 33-39 and 49-52 as being obvious over U.S. Patent No. 5,601,883 of Yamazaki in view of U.S. Patent No. 5,914,115 of Subramaniam, and optionally considering U.S. Patent No. 5,053,244 of Kieser and/or U.S. Patent No. 4,897,285 of Wilhelm.

Independent Claim 1:

Amended claim 1 recites a method of treating an *inner surface* of a tubular article having a lumen, which includes: generating a gaseous plasma within a spatially-localized region of space by electron cyclotron resonance, exposing at least a portion of *an inner surface* of the lumen of the tubular article to the plasma for a selected time period to treat the surface and *causing at least one surface modification selected from a group consisting of increased surface energy, crosslinking and chemical bond scission.* Subsequently, the treated surface is coated with a selected *bioactive* material. Support for the amendments can be found in the original claims and throughout the specification, specifically at page 8, paragraphs 1 and 3.

Yamazaki is directed to a microwave enhanced chemical vapor deposition method for coating the external surfaces of plastic articles with crystalline carbon films. The method disclosed by Yamazaki includes cleaning such a surface via exposure to a plasma generated in a gas by microwave energy and a magnetic field, and depositing carbon on the cleaned surface. Yamazaki, however, lacks any teaching or suggestion that its disclosed method may be used for cleaning or coating the *internal* surfaces of the articles.

Subramaniam is directed to providing covalently attached therapeutic coatings for surfaces of medical devices. Subramaniam teaches functionalizing a surface of a medical device with covalently bound thermochemically reactive groups. The surface is further contacted with

a bioactive agent that is thermochemically covalently coupled to the reactive group to form a therapeutically effective coating. To functionalize a surface of a medical device, Subramaniam oxidizes that surface by utilizing a plasma created via radiofrequency ("RF") glow discharge. Subramaniam, however, fails to teach or suggest the use of electron cyclotron resonance ("ECR") for generating the plasma.

The Examiner argues that since Yamazaki discloses applying its coating method to the surfaces of tubular articles such as "pen / pencil parts," items which have lumens, it is inherent that the gas would be present in the interiors of such articles. The Examiner combines this with the assertion that "Subramaniam provides plasma teaching were (sic) interior plasma treatment is desirable" to maintain that it is reasonable to expect that interior plasma treatment *can* occur in Yamazaki. Thus, the Examiner contends that Yamazaki together with Subramaniam provides "motivation to ensure" occurrence of interior plasma treatment as recited by the claimed invention. Hence, the Examiner considers the claimed invention as obvious over the combined teachings of Yamazaki and Subramaniam.

Applicants respectfully submit that the obviousness rejection of claim 1 falls short of the legal standards for the following reasons. The Court of Appeals for the Federal Circuit has held that "[w]hen an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references." *WMS Gaming Inc. v. Intl. Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999). "The suggestion to combine may be found in explicit or implicit teachings within the references themselves, from the ordinary knowledge of those skilled in the art, or from the nature of the problem to be solved." *Id.* Specifically, "the question is whether there is something in the prior art as a whole to suggest the desirability, and thus obviousness, of making the combination." *In re Rouffet, et al.*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998). Furthermore, the Federal Circuit has clarified that in order to prevent the use of hindsight based on the claimed invention when combining prior art references to create obviousness, "the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet, et al.*, 149 F.3d at 1357.

Neither Yamazaki or Subramaniam provides a motivation to combine its teachings with those of the other to arrive at the claimed invention.

As discussed previously, Yamazaki is only concerned with treating external surfaces of articles, and not their internal surfaces. While Yamazaki lists various objects to be coated including "ball pens" and "propelling pencils", the disclosure expressly states that the "entire *external* surface" of these objects is coated (emphasis added). *See* Col. 3, lns 40-45. Yamazaki fails to address in any manner whether the application of its method could extend to treating internal surfaces of these objects. Further, notwithstanding the Examiner's inherency argument, there is no indication in Yamazaki that the articles include openings through which the gas can contact their internal surfaces. Moreover, Yamazaki lacks any suggestion that it would be desirable or beneficial to apply its carbon coating, formed by ECR plasma, to an inner lumen surface of an article. In sum, Yamazaki does not provide any motivation to one of ordinary skill in the art to look to other teachings, such as those of Subramaniam, to extend its methods to ECR plasma treatment of inner surfaces of articles.

Conversely, Subramaniam does not provide any motivation to look to the teachings of Yamazaki to utilize an ECR plasma for treating the inner surfaces of its medical devices. Subramaniam does not recognize any deficiencies in utilizing a glow discharge plasma for treating surfaces of medical devices. In fact, Subramaniam's teachings are primarily directed to coating vascular stents that have relatively open structures – a vascular stent is formed as an expandable wire mesh. (*See e.g.* FIG. 5). As such, glow discharges provide adequate means to coat their surfaces. Accordingly, Subramaniam does not provide any motivation to consider other forms of plasma, such as an ECR plasma, for treating surfaces of articles, much less internal lumens of tubular articles.

In sum, one skilled in the art, without using the claimed invention as a blueprint, would not be motivated to combine Yamazaki with Subramaniam to arrive at a method of treating an inner surface of a tubular article having a lumen with an ECR generated gaseous plasma so as to cause at least one surface modification, and subsequently coating the treated lumen with a selected bioactive material, as recited by amended claim 1.

Moreover, Kieser and Wilhelm do not cure the shortcomings of Yamazaki and Subramanian. In particular, both Kieser and Wilhelm describe methods for *direct* deposition of a coating material from a plasma onto a surface, and not the two-step process of claim 1 that includes initially treating an inner surface of a lumen with an ECR plasma and subsequently coating the treated surface.

Accordingly, amended claim 1, and claims 4-8, 10-19, 21-28 and 31 that depend either directly or indirectly on claim 1, are patentable.

Independent Claims 33 and 50:

Amended claim 33 recites a method of treating an inner wall of an electrically non-conducting lumen, comprising the steps of: placing a selected portion of said lumen in a treatment zone, applying a magnetic field having a selected strength to the treatment zone, introducing a gas into said lumen within said selected portion, said gas being in contact with the inner wall of said selected portion, irradiating said gas with electromagnetic radiation having a frequency selected to be substantially equal to electron cyclotron frequency at said selected magnetic field strength so as to ionize said gas and create a plasma zone within said selected portion, said plasma treating said inner wall of the lumen so as to cause a physical and/or chemical modification of the inner wall. The modification comprises *at least one inner wall modification selected from a group consisting of increased surface energy, crosslinking and chemical bond scission.* The treated inner wall is subsequently coated with a selected *bioactive* material. Support for the amendments can be found in the original claims and throughout the specification, specifically at page 8, paragraphs 1 and 3.

Amended claim 50 recites a method of treating an inner surface of a lumen of each of a plurality of tubular articles, comprising: generating a gaseous plasma within a spatially-localized region of space by ECR, simultaneously exposing a portion of an inner surface of each of the articles to said plasma for a selected time period to treat the surfaces so as to physically and/or chemically modify them. The modification causes *at least one surface modification selected from a group consisting of increased surface energy, crosslinking and chemical bond scission.* Subsequently, the treated surfaces are coated with a selected *bioactive* material. Support for the

amendments can be found in the original claims and throughout the specification, specifically at page 8, paragraphs 1 and 3.

The arguments presented above with respect to amended claim 1 apply with equal force to establish that amended claims 33 and 50 are also patentable over the cited art. Accordingly, claims 34 – 39 that depend either directly or indirectly on claim 33, are also patentable.

Claims 49 and 51 were previously canceled and are thus no longer at issue.

In Paragraph 4 of the Office Action, claims 21-24 and 26-28 are rejected as being obvious over Yamazaki in view of Subramanian, optionally considering Kieser or Wilhelm, and further in view of U.S. Patent No. 4,927,676 of Williams, U.S. Patent No. 5,942,277 of Makker and U.S. Patent No. 5,486,357 of Narayanan.

These claims depend either directly or indirectly on amended claim 1, and hence incorporate its patentable features. As discussed in detail above, claim 1 is not rendered obvious by Yamazaki and Subramaniam, as there is no motivation to combine their teachings. Further, the teachings of Williams, Makker and Narayanan fail to cure the shortcomings of Yamazaki and Subramanian. Williams, which is generally directed to forming a confluent layer of endothelial cells over a polymeric substrate functionalized by exposure to a nitrogen-containing plasma, does not teach utilizing an ECR plasma for functionalizing the substrate. Similarly, Narayanan fails to teach the use of an ECR plasma for treating a surface. Rather, it discloses the use of an RF generated plasma to treat polymeric surfaces. Likewise, Makker teaches employing an RF generated plasma, rather than an ECR plasma, to treat a polymeric surface.

Accordingly, claims 21 – 24 and 26 – 28 that depend either directly or indirectly on amended claim 1, are patentable.

In Paragraph 5, the Office Action rejects claims 1, 4, 8, 10, 16-17, 19, 21-22, 24-25, 27-28, 31, 33, 36 and 49-52 as being anticipated by U.S. Patent No. 6,136,389 of Conover et al.

Conover discloses a method for preparing thin films of noble metals on porous substrate surfaces in which metal containing monomer or comonomer precursors are dissociated by a glow discharge and deposited as a platinized coating over the surface. Conover further indicates that subsequent to forming the platinum coating, a plasma polymerized coating of monomers, such as propylene, siloxanes or silanes, can be applied to the substrate.

Conover, however, does not teach initially treating a surface with an ECR plasma to cause a *selected* modification to that surface, such as causing increased surface energy, cross-linking and chemical bond scission; and subsequently coating the modified surface with a bioactive material. Rather, Conover relies on forming a platinum layer on the surface on which subsequent plasma-assisted coatings can be applied, rather than modifying the surface *itself.* Moreover, the subsequent coatings do not include *bioactive* materials (for example, anti-biotics, anti-coagulants, anti-thrombogenic or other therapeutic compounds), as required by amended claim 1.

Accordingly, amended claim 1, and claims 4, 8, 10, 16, 17, 19, 21-22, 24-25, 27-28, and 31 which depend either directly or indirectly thereon, distinguish over Conover. Further, similar arguments apply to establish that amended claim 33, which also recites a plasma treatment of an inner wall to cause *at least one selected inner wall modification* and a subsequent coating of the treated surface with a *bioactive* material, is also patentable over Concover. Likewise, claims 36 and 52 are patentable as they depend on claim 33 and hence incorporate its patentable features.

Similar arguments also apply to establish that amended claim 50 distinguishes patentably over Conover. In particular, similar to claim 33, claim 50 recites that plasma treatment of the inner surfaces modifies the inner surfaces by causing *at least one selected surface modification.* In addition, it recites subsequently coating the treated inner surfaces with a *bioactive* material – a feature not taught by Conover.

Claims 49 and 51 were previously canceled and are thus no longer at issue.

In Paragraph 6, the Office Action rejects claims 5-7, 11-15, 22, 25-26, 34-35 and 37 as being obvious over Conover et al.

Claims 5-7, 11-15 , 22, and 25-26 depend either directly or indirectly on amended independent claim 1, and claims 34-35 and 37 depend on amended independent claim 33. As discussed above, claims 1 and 33 distinguish patentably over Concover, and hence so do their associated dependent claims, which incorporate their patentable features.

In paragraph 7, the Office Action rejects claims 53-58 as being obvious over Conover et al. in view of Wilhelm and U.S. Patent No. 5,967,257 of Kanai.

Independent claim 53 recites a method of selectively treating an internal surface of a tubular article having a lumen, comprising: placing at least a portion of the tubular article in a treatment zone to which a magnetic field having a selected strength is applied, introducing a gas into the article's lumen so as to generate an internal pressure different than an external pressure to which an outer surface of said portion is exposed, irradiating the tubular portion with electromagnetic radiation having a frequency selected to be substantially equal to electron cyclotron frequency at said magnetic field strength so as to generate a plasma within said lumen portion for treating a surface thereof, wherein said external pressure inhibits formation of a plasma in proximity of the outer surface, and subsequently, coating said treated lumen surface with a selected material.

Independent claim 54 recites a method of selectively treating an outer surface of a tubular article having a lumen, which includes: placing at least a portion of the tubular article in a treatment zone containing a gas at a selected pressure such that an outer surface of at least a portion of said article is exposed to said gas, causing an internal pressure within a lumen of said tubular portion to be different than said treatment zone pressure, generating an ECR plasma within said treatment zone so as to treat said outer surface by exposure to said plasma while said internal pressure inhibits formation of a plasma within said lumen portion, and subsequently, coating said treated outer surface with a selected material.

The Examiner argues that Conover is clearly suggestive of the use of different pressures to selectively treat an inner or an outer surface of a tubular article. In support, the Examiner points to a passage in Conover that states "techniques known in the art for 'single side' or 'counter flow' low pressure chemical vapor deposition (LPCVD) ... can be modified to obtain

controlled platinization layer or zone within the interior wall of the substrate tubing, for deposition at a specific location along the wall." (Col. 5, lns 19-25). The Examiner contends that this "terminology suggests that flow hence pressure is involved."

The Examiner does not, however, indicate with any degree of specificity how the counter flow LPCVD would suggest, much less teach, the claimed subject matter. Applicants respectfully submit that the mere fact that gas flow may be involved in the counter flow LPCVD does not rise to the level of teaching required under legal standards to render the claimed subject matter obvious.

Further, Wilhelm is not concerned with differential coating of an inner and an outer surface of a tubular article. Rather, it is directed to *direct* plasma coating of an inner surface of a microwave waveguide. As such, it does not provide any teaching pertinent to the subject matter of claims 53. Further, Kanai does not cure the shortcomings of Conover and Wilhelm in this regard. In particular, the passage in Kanai to which the Examiner refers simply describes utilizing a mesh member to prohibit microwave leakage through an exhaust port of a CVD apparatus while permitting gas exhaust through the port.

Hence, claim 53 distinguishes patentably over the cited art.

Similar arguments apply to establish that independent claim 54, and claims 55-58 dependent thereon, are also patentable over the cited art.

In view of the above remarks, Applicants request reconsideration and allowance of the application.

Dated: March 7, 2006

Respectfully submitted,

By _____
Reza Mollaaghababa
Registration No.: 43,810
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
(617) 439-2514
(617) 310-9514 (Fax)
Attorney for Applicant

1508415.1